REMARKS

Claims 2-6, 8, 9, 11, 13, 14, 16-19, 21, 22, 24, 31-33, 35, 36 and 73-79 remain in this application. Claims 8, 31, and 73 have been amended to recite that the taste masking agent is comprised of an insoluble film forming polymer and a non-enteric, water soluble polymer. Support for this amendment can be found throughout the specification, including page 4, lines 30-34. Claim 16 has been amended to now depend from claim 8 and claim 75 has been amended to fix a typographical error. New claims 77-79 have been added, and support for these new claims can be found on page 4, lines 30-34 and claim 76. Accordingly, no issues of new matter are believed to be raised by the above amendments to the claims. Applicants reserve the right to pursue the previous claim scope in subsequent continuation/divisional patent applications.

Claim Objection

Claim 24 was objected to pursuant to 37 CFR 1.75 as being a substantial duplicate of claim 16. See pages 2-3 of the Office Action. As indicted above, Applicants have amended claim 16 to now depend from claim 8. Accordingly, Applicants respectfully request that this objection has been overcome.

Rejections Under 35 USC 102

Claims 4, 6, 8-9, 11, 14, 31, 35, and 73 were rejected under 35 USC 102(b) as being anticipated by Yang et al. (US 5,576,022). See Pages 3-6 of the Office Action. Yang et al. discloses a controlled release tacrine drug delivery system. See, e.g., abstract of Yang et al. As noted on pages 4-5 of the Office Action, Yang et al. discloses sustained release pellets that comprise a "sustained coating" containing ethylcellulose and an "overcoat coating" containing HPMC and polyethylene glycol in Formulation No. 40 on col. 14. However, the ratio of HPMC to polyethylene glycol in this formulation is 2.15:0.36 or 86:14, which is not within the range of 80:20 to 20:80 as recited in the pending claims of the present application.

Further, as indicated above, Applicants have now amended independent claims 8, 31, and 73 to now recite that the particles of the pending claims comprises a non-enteric, water-soluble polymer

in the first coating layer (e.g., allowing for an immediate release profile of the active ingredient in the core), which is different from the sustained release particles disclosed in Yang et al.

Thus, Applicants respectfully request that this rejection under 35 USC 102(b) be withdrawn.

Rejections Under 35 USC 103

Claims 2, 4-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31, 33, 35-36, and 73-76 were rejected under 35 USC 103(a) as being unpatentable over CA 2,068,366 in view of Kanai et al. (US 4,868,183) and Uchida et al. (US 5,215,999) in further view of Yang et al. (US 5,576,022). See Pages 7-15 of the Office Action. As discussed above with Yang et al., the microcapsules of CA 2,068,366 also exhibit a reduced dissolution profile. See, e.g., abstract and claim 1 of CA 2,068,366.

Further, as noted on pages 9-10 of the Office Action, CA 2,068,366 fails to disclose particles containing the second coating layer as recited in the pending claims. According to the Office Action on page 10, "It is for this reason that Kanai et al., Uchida et al., and Yang et al. are added as secondary references."

As discussed above, Yang et al. fails to disclose particles having a non-enteric, water-soluble polymer in the first coating layer as recited in the pending claims of the present application, nor do the particles have a "weight ratio of water soluble and/or water swellable film forming polymer to anti-grit agent in the second coating layer is in the range of about 20:80 to about 80:20."

While Kanai et al. may disclose a tablet coated with HPMC and polyethylene glycol (col. 39, lines 1-27), it does not disclose particles coated with such ingredients. The mere coating of tablets will not provide the anti-grit benefit to the underlining particles when the tablet is chewed as the tablet coating is broken upon chewing. Merely coating the outside of the tablets would not remove the gritty, sandy texture of the resulting particles after the tablet is chewed and the outside tablet coating is broken. There is no disclosure, or even suggestion, that such a coating can be used for particles, let alone particles that already have a first coating as set forth in the pending claims. Furthermore, Kanai et al. is silent to chewable tablets.

Similarly, Uchida et al. also only discloses the coating of tablets with HPMC and polyethylene glycol (col. 64, lines 1-19), not the coating of particles. As discussed above, the mere coating of tablets will not provide the anti-grit benefit to the underlining particles when the

tablet is chewed as the tablet coating is broken upon chewing. Merely coating the outside of the tablets would not remove the gritty, sandy texture of the resulting particles after the tablet is chewed and the outside tablet coating is broken. There is no disclosure, or even suggestion, that such a coating can be used for particles, let alone particles that already have a first coating as set forth in the pending claims. Furthermore, Kanai et al. is silent to chewable tablets.

Thus, in conclusion, none of the four cited references, alone or in combination, disclose or even suggest the particles, the method of making such particles, and the dosage forms containing such particles as recited in the pending claims. Specifically, as noted in the Office Action, the primary reference CA 2,068,366 fails to disclose particles containing the second coating layer as recited in the pending claims. Further, one of ordinary skill in the art would not look to combine the coated particles teachings of CA 2,068,366 or Yang et al. with either Kanai et al. or Uchida et al. as both Kanai et al. and Uchida et al. disclose tablet coatings, not particle coatings.

Further, as recited in Example 4 of the present application, the application of this second water-soluble layer were unexpectedly found to improve the resulting particles, as compared to the particles with only the taste-masking layer, when used in a chewable tablet. As recited in Example 4, "[b]oth tablets were found to have had a similar taste, with a very slight bitterness detected by most panelists. The tablets from Example 1 [e.g., tablets made without the water-soluble layer] were found to have had a perceptible grittiness, which ranged from 'slight' to 'obvious,' and a rough surface. By contrast, the 'texture-masked' particles of the present invention produced in accordance with Example 3 were found to have had no grittiness, a smooth texture and a 'good melt-away,' i.e. the tablet was rapidly cleared from the oral cavity with minimal chewing required." Further the use of layer was not found to retard the dissolution of the active ingredient as "100% of the acetaminophen active ingredient was released from the tablets of Example 1 and Example 3 in 45 minutes." Such an unexpected result was not taught, nor suggested, by CA 2,068,366. nor by Yang et al., Kanai et al, or Uchida et al.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

Conclusion

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the presently presented claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/MCP0231USNP/WEM.

Respectfully submitted,

By: /William E. McGowan/
William E. McGowan
(Attorney for Applicants)
Reg. No. 39,301

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2197